

ATTACHMENT A
Remarks

Claims 1-39 stand pending in the present application. Claim 10 has been amended to cancel multiple dependency.

END REMARKS

ATTACHMENT B

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1) (Original) Apparatus for the maneuvering of flexible catheters in the human cardiovascular system, characterized in that it comprises:

- Means (2), in the form of an arm for example, for positioning, aiming and correct orientation with respect to the patient of a device (R) for remote manipulation of the catheter;
- A device (R) which supports at least one portion of the catheter (C) and which comprises remotely controllable actuators, for transmitting to the said catheter at least a longitudinal movement of advance or withdrawal and/or a rightward or leftward rotary movement about its longitudinal axis;
- A control and monitoring unit (47) located in a remote position and protected in a shielded environment (48), by means of which the operator can remotely control and monitor the operation of the said device (R) which carries out the servo-controlled maneuvering of the catheter (C) in the patient's body;
- Means (46) for the operational remote connection of the said servo-controlled device (R) to the said control and monitoring unit (47).

2) (Original) Apparatus according to Claim 1, characterized in that it comprises means which, in response to a remote command from the said control unit (47), can execute a controlled forward or backward longitudinal movement and if necessary a rightward or leftward rotation of the metal stylet (S) normally present in the catheter (C), to facilitate and correct the advance of the said catheter in the patient's body.

3) (Original) Apparatus according to Claim 1, characterized in that it comprises a disposable device (44) for the ligation of the access vessel for the introduction of the

catheter, which has the function of controlling the haemostasis and/or supporting the end of the said vessel into which the catheter (C) is to be inserted, while allowing the catheter to undergo the necessary sliding and rotary movements, this device (44) being supported by suitable means and being, for example, associated with means which enable the closing tension of the ligature (44) exerted on the vessel to be increased or reduced by remote control from the control and monitoring unit (47) located in the protected booth (48).

4) (Original) Apparatus according to Claim 1, in which all the parts intended to come into contact with the catheter (C) and with any corresponding stylet (S) are provided in a disposable component designed for rapid and removable mounting on a box (1a) which contains all the actuators and means necessary for the operation of the said apparatus by remote control.

5) (Original) Apparatus according to Claim 4, characterized in that the catheter is of the steerable type, and the said apparatus comprises means driven by remotely controllable actuators, also housed in the box (1) containing the drive equipment, these actuators guiding the said catheter by transmitting to the tip and to the body of the said catheter the necessary bending and/or rotation to reach the desired position within the cardiovascular system.

6) (Original) Apparatus according to Claim 1, in which the catheter manipulation device (R) comprises units, for example pairs of rollers (5, 105, 5', 105') which are opposed, parallel to each other and orthogonal to the catheter, or equivalent means, such as belts, provided for example with treads with concave profiles, which enclose the catheter in a sufficiently well distributed way and which are made from material and in shapes such that they have a high coefficient of friction in relation to the said catheter, while treating the catheter as gently as possible, additional means being provided for transmitting to the said rollers a rotary movement about their axes for moving the

catheter longitudinally forwards or backwards or for transmitting to the said rollers a movement of rotation or revolution about the longitudinal axis of the catheter, to rotate the said catheter about its axis to the right or to the left.

7) (Original) Apparatus according to Claim 6, in which some of the said rollers or belts which control a portion of the catheter are mounted statically and in a projecting way on a support wall (204) and are connected to a source of rotation, while the rollers or belts opposite the static ones are mounted so that they can oscillate on the said support wall, in opposition to elastic means (20), in order to grip the catheter by friction, to enable them to act on catheters of different diameters and to enable them to be moved away as necessary from the static rollers or belts whenever the catheter has to be inserted between the said movement rollers or belts or withdrawn therefrom, suitable means (21) being provided to facilitate this movement away.

8) (Original) Apparatus according to Claim 7, in which the wall (204) which carries the rollers or belts for supporting and moving the catheter has at its end a right-angled wall (104) which is fixed perpendicularly to the open end of a hub (3) through which the catheter passes longitudinally and is therefore aligned tangentially to the gripping surfaces of the said rollers or belts, this hub being inserted axially into a hollow rotation shaft (10) of the apparatus, supported rotatably by the base of the box (1), the hub being keyed and locked axially in this shaft by means of couplings and suitable means (11), in such a way that all the parts of the apparatus designed to come into contact with the catheter can be interchanged and are disposable, the said box (1) housing in a shielded position the necessary drive units (17, 16) for transmitting to the said rollers or belts both the rotary movement about their axes and the movement of rotation or revolution about the axis of the catheter.

9) (Original) Apparatus according to Claim 8, in which the hollow shaft (10) is connected by a drive transmission system (15) to a corresponding drive unit (16) which

causes the rotation of the catheter in both directions and which is flanged on to the base of the box (1) of the apparatus, the said shaft (10) being mounted rotatably by means of bushes or bearings (12) in a second tubular shaft (13) supported rotatably by the said base of the box (1) by means of bushes or bearings (14), the pinion (118) which transmits the drive to the pinion (9) of the disposable part of the apparatus being keyed on one end of the said shaft (13), while a pinion (18) connected to the drive unit (17) for advancing and withdrawing the catheter is keyed on the other end of the said shaft (13).

10) (Currently Amended) Apparatus according to ~~any one or more of the preceding claims~~ claim 1, in which means are provided for enabling the catheter to be rapidly released at any time from the opposing manipulation rollers or belts, and also from the hollow shaft or shafts of the said apparatus, in such a way that it can be controlled freely and directly by the operator.

11) (Original) Apparatus according to Claim 1, in which the catheter manipulation device (R) comprises at least one specific set of rollers or belts (25, 125) for the longitudinal movement of the catheter, and a different set of rollers or belts (34, 134) expressly designed to rotate the said catheter about its longitudinal axis.

12) (Original) Apparatus according to Claim 11, characterized in that it comprises a box (1) connected to the positioning arm (2) and housing the drive equipment all means required for the remote operation of the said apparatus, this box having fixed to it, removably and with a downward extension, a parallelepipedal and internally hollow body (23), with rounded edges and corners, whose lower end, designed to be positioned close to the patient's body, is provided with a transverse oblique blind groove or channel (24), into which the catheter (C) is inserted, this channel being inclined in such a way that the catheter is impelled by gravity into the innermost part of the said channel, in which the rollers or belts for driving and/or rotating the catheter operate.

13) (Original) Apparatus according to Claim 12, in which the portion of catheter passing through the said channel (24) bears on at least one orthogonal roller (125), having a tread with a curved profile, mounted statically and rotatably in the body (23), a second roller (25) being provided above and parallel to this roller, the shaft (26) of the second roller being supported rotatably by a sliding block (27) guided vertically in the said body (23) and pushed upwards by an elastic means (28), in such a way that the said roller (25) does not normally interact with the catheter, a vertical shaft (29) being mounted rotatably on the sliding block (27) and having its lower end connected by gearing, of the worm gear (129) and helical gear (229) type for example, to the shaft (26) of the said roller (25), the upper end of the said shaft (29) having a toothed coupling (329) for rapid and removable keying to a power take-off (30) guided axially in a support (31) of the box (1) and being connected by means of gearing (32) to the drive unit (17) housed in the said box (1), together with an actuator (33) whose rod (133) interacts with the said power take-off (30), the whole being arranged in such a way that when the rod (133) is raised the drive roller (25) is located away from the catheter (C) which can thus be inserted into the guide channel (24) or removed therefrom, while when the said rod (133) is lowered in opposition to the spring (28) the driving roller (25) interacts frictionally with the catheter whose lower part bears on the driven roller (125) and the said catheter can be made to advance or withdraw by the action of the drive unit (17).

14) (Original) Apparatus according to Claim 12, in which the portion of catheter passing through the guide channel (24) also bears between and on a pair of rollers (34) which are parallel to each other and to the said catheter, and which are supported in a free-running way by the body (23), and a third driving roller (134) is provided in a symmetrical and parallel arrangement above the said rollers (34), the axle (35) of the third roller being supported rotatably by a sliding block (36) which is vertically movable in the said body (23) and is pushed upwards by an elastic means (37), and which carries a rotatable vertical shaft (38) which is mechanically connected by gearing (39,

40) in its lower part to the axle of the driving roller (134), the upper end of the shaft (38) being provided with a toothed coupling (138) for rapid and removable keying to a power take-off (41) which is guided axially in the said support (31) of the box (1) and which is connected by means of gearing (42) to the drive unit (16) housed in the said box (1) together with an actuator (43) whose rod (143) interacts with the power take-off (41), the whole being arranged in such a way that, when the said rod is raised, the driving roller (134) is raised from the catheter (C) which can thus be inserted into the guide channel (24) or removed therefrom, while when the said rod (143) is lowered in opposition to the spring (37) the driving roller (134) interacts frictionally with the catheter whose underside bears on the driven rollers (34) and the said catheter can be made to rotate about its axis by the action of the drive unit (16), with rightward or leftward rotation.

15) (Original) Apparatus according to Claim 12, characterized in that it comprises a device (52) for fixing the rear end of the catheter (C) removably, rotatably and rapidly to an appendage (123) of the body (23) of the disposable part of the apparatus, in which appendage there is provided a vertical channel (53) into which can be inserted the free rear portion of the stylet (S) of the catheter, which is gripped between a pair of parallel driving rollers (54) sprung with respect to each other and provided with a temporary opening device for the insertion of the stylet between them and its extraction therefrom.

16) (Original) Apparatus according to Claim 15, in which the driving rollers (54) of the stylet (S) are connected by gearing (55) to a vertical shaft (56) supported rotatably by the body (23) of the disposable part of the apparatus and having a portion projecting above this body and provided with a toothed coupling (156) which is connected to a power take-off (57) which in turn is connected by gearing (58) to a drive unit (59) which is also housed in the box (1), the whole being arranged in such a way that the rightward or leftward rotation of this unit causes the controlled rotation in both directions of the said driving rollers (54) which provide the necessary longitudinal movement of the stylet (S) of the catheter (C).

17) (Original) Apparatus according to Claim 9, in which the drive units of the rotating type (16, 17, 59) housed in the box (1) comprise reversible electric motors suitable for remote electronic speed and phase control, for example stepping or brushless motors or other suitable types, while any linear actuators located in the said box for executing other necessary movements are provided with encoders and/or are also equipped for remote control.

18) (Original) Apparatus according to Claim 1, in which the remote control unit (47) comprises safety means to ensure the safety of the operation of the remote maneuvering of the catheter in the patient's body, and to enable this operation to be completed by remote control, means being provided for this purpose and consisting for example of means for measuring the parameters relating to the force used to advance and/or rotate the catheter during the remote manipulation with the said apparatus, in such a way as to transmit to the operator an equivalent of the sensitivity which the said operator had previously in the direct manipulation of the catheter, provision being made for the possible additional use of these parameters for the automatic control of the operation of the apparatus, for example in order to stop the current operation and to reverse it if necessary when excess force continuing for more than a specified time interval is detected.

19) (Original) Apparatus according to Claim 1, in which means (149) are provided in the remote shielded station (48) from which the operator (Q) operates with the unit (47) for controlling and monitoring the said apparatus, for activating and for detecting remotely the operation of the viewing system (49), for example the X-ray fluoroscopy system, used on the patient to display the position assumed progressively by the catheter in the body of the said patient, and at least one screen (150) can be provided in the said station (48) with any necessary controls, connected to at least one video

camera (50) placed near the patient (P), for example on the box (1), for observing at least the region of the said patient into which the catheter (C) is inserted.

20) (Original) Apparatus according to Claim 1, in which means (51) for measuring important physical parameters of the patient being treated are also provided in the remote shielded station (48) from which the operator (Q) operates with the remote control and monitoring unit (47) of the said apparatus.

21) (Original) Apparatus according to Claim 1, in which the said apparatus (R) and the ligature device (25) for controlling haemostasis can be connected to an interface system (26) suitable for communication over a distance with the control unit (47) located in the remote shielded room (48) in which the operator (Q) operates, by means of wire-based or wireless connection and/or communication systems (46).

22) (Original) Apparatus according to Claim 1, in which the systems for the remote control of the said apparatus can comprise voice control systems.

23) (Original) Apparatus according to Claim 1, in which the means, of the arm type (2) for example, for positioning the said apparatus with respect to the patient are such that they remain fixed when the said apparatus operates, or can be movable and adjustable by remote control.

24) (Original) Apparatus according to Claim 1, in which a rechargeable electrical battery for the autonomous operation, if necessary, of the said apparatus can be mounted in the box (1) or in another suitable position, in addition to the electronic card or cards.

25) (Original) Apparatus according to Claim 1, characterized in that it comprises a pair of rollers (W1, W2) parallel to each other and orthogonal to the catheter, connected

wholly or partially to means (Z1) for rotation in both directions, for longitudinally advancing or withdrawing (Z10) the said catheter, and connected to means for transmitting to at least one of the said rollers an axial movement (Z2) in one direction or in the opposite direction, in such a way as to cause the rotation (Z20) of the said catheter by rolling between the rollers, so that the catheter rotates about its axis either to the right or to the left.

26) (Original) Apparatus according to Claim 25, characterized in that each of the rollers (W1, W2) has a cylindrical lateral surface, with a straight generatrix, in such a way that the catheter can be rotated by rolling on them.

27) (Original) Apparatus according to Claim 25, characterized in that the means which transmit to one of the rollers (W1) the axial movement which causes the rightward or leftward rotation of the catheter comprise means for transmitting an equal axial movement in the opposite direction to the other roller (W2), the whole being done in such a way that the catheter (C) rotates about its axis without transverse movement.

28) (Original) Apparatus according to Claim 1, characterized in that, if the catheter (C) has an internal metal stylet (S) acting as a guide mandrel, the said robotic apparatus is provided with two maneuvering units (U1, U2), each of which can transmit rightward or leftward rotary movements and/or longitudinal forward or backward movements to the catheter and to the guide mandrel.

29) (Original) Apparatus according to Claim 28, in which each maneuvering unit (U1, U2) carries a pair of parallel rollers (W1, W2) which grip the catheter (C) or the end of the said guide mandrel (S) in an orthogonal way and which can be driven selectively and independently, both in respect of the longitudinal movement and the rotation of the said catheter (C) and/or the guide mandrel (S).

30) (Original) Apparatus according to Claim 29, characterized in that the pair of rollers (W1, W2) for interacting with the catheter (C) are made or covered on their circumferences with a material suitable for the gentle frictional interaction with the said catheter, for example a suitable elastomeric material.

31) (Original) Apparatus according to Claim 29, characterized in that the pair of rollers (W1, W2) for interacting with the guide mandrel (S) are characterized on their circumferences by sleeves of material suitable for the gentle frictional interaction with the said guide mandrel, for example a steel sleeve with a satin external surface.

32) (Original) Apparatus according to Claim 27, characterized in that one of the rollers (W1) is the driving roller and is keyed on the end of a shaft (60) mounted rotatably and with the possibility of axial movement in a supporting body (62) from which the said shaft projects with an end portion opposite the end carrying the roller, for rapid and removable keying to a hollow shaft (64) which projects from the base (101) of the box (1) containing the drive equipment of the robotic apparatus in question, the said support (62) being fixable rapidly and removably to this base by its own base piece (162), the said hollow shaft (64) being connected to a first geared motor unit (65) with an electric motor, of the stepping type for example, fixed on a sliding block (66) which slides while being guided parallel to the said shaft (64), on guides (166) fixed on the said base (101) and to an opposing base piece (266) on which is mounted a second geared motor unit (67) with an electric motor, of the stepping or other type with electronic speed and phase control for example, which rotates a nut (68) interacting with a worm gear (168) integral with the sliding block (66) or with one of the components installed thereon, the whole being arranged in such a way that the activation of the said first drive unit (65) causes the rightward or leftward rotation (Z1) of the roller (W1), while the activation of the second drive unit (67) causes the axial movement (Z2) of the said roller (W1), a cylindrical rack (69) which engages with a pinion (70) mounted freely

rotatably in a suitable seat of the supporting body (62) being keyed on the intermediate portion of the shaft (60) of the roller (W1).

33) (Original) Apparatus according to Claim 32, characterized in that the other roller (W2) is driven and is keyed on the end of a shaft (160) which is mounted rotatably and with the possibility of axial movement in a bush (71) which has, on its end opposite that facing the said roller, an appendage (171) pivoted transversely in the support body (62) and pushed by a spring (73) in such a way that the said roller (W2) is pressed against the roller (W1) to provide the necessary secure frictional grip of the catheter (C) or of the guide mandrel (S) located between the said rollers (W1, W2), a cylindrical rack (169), identical to the rack (69) of the shaft of the driving roller, which engages with the said pinion (70) which passes through a lateral aperture in the said bush (71), being keyed on the portion of shaft (160) of the driven roller lying within the said bush (71), the whole being arranged in such a way that, by the action of the said rack and pinion system (69, 70, 169) any axial movement imparted to the roller (W1) by the corresponding drive unit (67) results in a corresponding axial movement of the driven roller (W2) through an equal distance and in the opposite direction.

34) (Original) Apparatus according to Claim 33, characterized in that an eccentric (74) is mounted rotatably in the support body (62), orthogonally to the shafts (60, 160) of the rollers (W1, W2), and interacts with the said bush (71) and can be rotated by at least one external end lever (75) by means of which the part of the said eccentric (74) having the greatest eccentricity can be brought into contact with the said bush (71) when required to move the driven roller (W2) away from the driving roller (W1), through a distance sufficient to enable the catheter (C) or the guide mandrel (S) to be removed from the said rollers (W1, W2) or inserted between them.

35) (Original) Apparatus according to Claim 26, characterized in that there is provided, upstream and/or downstream of each pair of rollers (W1, W2), a loop (76) with

a slot (176) in which the catheter (C) or the guide mandrel (S) slides in a guided way, to provide a correct initial positioning of these components with respect to the corresponding pair of movement rollers.

36) (Original) Apparatus according to Claim 35, characterized in that the slot (176) of the said guide loop or loops (76) opens orthogonally to the axes of the rollers (W1, W2) and preferably in the direction of the driven roller (W2).

37) (Original) Apparatus according to Claim 35, characterized in that the slot (176) of the said guide loop or loops (76) opens parallel to the axes of the rollers (W1, W2) and in the direction in which the catheter (C) or the guide mandrel (S) is inserted into it when these components are located between their pair of controlling rollers (W1, W2), removable means being provided for temporarily closing the open side of the said slot in order to retain therein the component to be guided (C, S).

38) (Original) Apparatus according to Claim 37, characterized in that the means for removably closing the slots (176) of the guide loops (76) can consist of the suitably shaped branches of the lever (75) which causes the rotation of the eccentric (74) which temporarily moves the sprung driven roller (W2) away from the driving roller (W1), for the stage of insertion of the catheter (C) or the guide mandrel (S) between these rollers.

39) (Original) Apparatus according to Claim 29, characterized in that the two units (U1, U2) for maneuvering the catheter (C) and the guide mandrel (S) are positioned on a single disposable supporting body (62) which can be fixed removably to the base piece (101) of the box (1) housing the drive equipment, which is associated with the positioning and supporting arms (2) of the said robotic apparatus, the said units being positioned at different heights and close to each other, the unit (U1) in the lower position being designed to interact by means of its rollers (W1, W2) with the body of the catheter

(C), while the unit (U2) in the higher position interacts by means of its rollers (W1, W2) with the guide mandrel (S) of the said catheter.